



U.S.S.N. 09/538,106

AMENDMENTS TO THE CLAIMS

Claim 1 (withdrawn).

2. (currently amended) A method for detecting malignant carcinoma, comprising:

(a) obtaining a tissue sample from a patient;

(b) determining the level of a p63 ~~gene product protein~~ in said patient sample using a p63 binding protein;

(c) comparing the level of said p63 ~~gene product protein~~ in said patient sample with the level of said p63 ~~gene product protein~~ in a control sample of cells;

wherein a lower level of said p63 ~~gene product protein~~ in said patient sample as compared to the control sample is indicative of the presence of malignant carcinoma.

3. (original) A method of claim 2, wherein said malignant carcinoma is carcinoma of the cervix, breast, salivary gland and/or prostate gland.

4. (previously amended) A method of claim 2, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180, sub-columnar reserve cells and human foreskin keratinocytes.

5. (currently amended) A method of claim 2, wherein the level of said p63 ~~gene product protein~~ is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.

6. (currently amended) A method for detecting cancer in tissues containing sub-columnar reserve cells, comprising:

(a) obtaining a tissue sample from a patient;

(b) determining the level of a p63 ~~gene product protein~~ in said patient sample using a p63 binding protein;

(c) comparing the level of said p63 ~~gene product protein~~ in said patient sample with the level of said p63 ~~gene product protein~~ in a control sample of cells;

wherein a lower level of said p63 gene product protein in said patient sample as compared to the control sample is indicative of the presence of cancer in said tissues.

7. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising cervical tissue, breast tissue, and/or prostate gland tissue

8. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising kidney, testis, adrenal gland, brain, spleen, and thymus.

9. (original) A method of claim 6, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180 and human foreskin keratinocytes.

10. (currently amended) A method for distinguishing cervical squamous carcinoma from cervical small cell undifferentiated carcinoma, comprising:

(a) obtaining a cervical tissue sample from a patient;

(b) determining the level of a p63 gene product protein in said patient sample using a p63 binding protein;

(c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of cervical squamous carcinoma cells;

wherein a decrease in the lower level of said p63 gene product protein in said patient sample as compared to the control sample is indicative of small cell undifferentiated carcinoma.

Claims 11 and 12 (withdrawn)

13. (original) A kit for diagnosing malignant carcinoma comprising a p63 specific antibody.

14. (original) A kit of claim 13, wherein said antibody is selected from the group comprising a TAp63-specific antibody and a Δ Np63-specific antibody.

15. (currently amended) The method of claim 2, wherein said p63 gene product protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14),

TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

16. (currently amended) The method of claim 10, wherein the level of said p63 gene product protein is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.

17. (currently amended) The method of claim 10, wherein said p63 gene product protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14), TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

18. (currently amended) A method for distinguishing benign prostate lesions from malignant prostate lesions, comprising:

(a) obtaining a prostate tissue sample from a patient;

(b) determining the level of a p63 gene product protein in said patient sample using a p63 binding protein;

(c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of basaloid prostate cells;

wherein a decrease in the lower level of said p63 gene product protein in said patient sample as compared to the control sample is indicative of small cell undifferentiated carcinoma.

19. (currently amended) The method of claim 18, wherein the level of said p63 gene product protein is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.

20. (currently amended) The method of claim 19, wherein said p63 gene product protein is selected from the group consisting of TAp63 α (SEQ ID NO: 13), TAp63 β (SEQ ID NO: 14), TAp63 γ (SEQ ID NO: 15), Δ Np63 α (SEQ ID NO: 16), Δ Np63 β (SEQ ID NO: 17) and Δ Np63 γ (SEQ ID NO: 18).

21. (currently amended) The method of claim 19, wherein the level of said p63 gene product protein in said patient sample is at least 2000-fold lower than the level of p63 gene product protein in said control sample.

Claim 22 (withdrawn).

23. (new) The method of claim 2, wherein said p63 binding protein is a p63 specific antibody.

24. (new) The method of claim 2, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOS: 13-24.

25. (new) The method of claim 6, wherein said p63 binding protein is a p63 specific antibody.

26. (new) The method of claim 6, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOS: 13-24.

27. (new) The method of claim 10, wherein said p63 binding protein is a p63 specific antibody.

28. (new) The method of claim 10, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOS: 13-24.

29. (new) The method of claim 18, wherein said p63 binding protein is a p63 specific antibody.

30. (new) The method of claim 18, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOS: 13-24.